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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,823	07/10/2006	James Gavin Burnet	J7175(C)	3927

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/551,823

Applicant(s)

BURNET ET AL.

Examiner

Frederick Krass

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 12/8/05; 11/25/05.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Art Unit: 1614

Specification

The examiner requests that applicant amend the first line of the specification to refer to the claim for priority to PCT/EP04/02849.

Claim Informalities

The following informalities are noted and should be corrected in responding to this Office action:

Claim 10, second line, the indefinite article "a" should be inserted before --- dispersant ---.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1614

1) The term "substantially" in claim 1 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. (The specification merely states that "ingredients which do not necessarily have an intrinsic thickening effect may be added either before or together with the thickening mixture" (page, first paragraph), but never defines the term "substantially" per se).

2) Claim 3, the recitation of "100%" is non-sequitur since the flavor could not comprise the entire oral composition as recited by claim 1. Correction is required.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-3, 6-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamane et al (USP 6,149,894).

Patentees disclose methods for manufacturing toothpastes in which 0.1 to 5% by weight thickener is added to a water/humectant liquid vehicle after addition of an

Art Unit: 1614

abrasive slurry (column 1, last paragraph). The preferred abrasive slurry comprises water, 20 to 75% by weight calcium carbonate, and a dispersant (column 2, lines 27-50). Useful thickeners include conventional products such as carboxymethylcellulose, carragenin, and colloidal silicas (see the passage bridging column 2, line 54 to column 3, line 11); various other conventional ingredients (surfactants, fluorides, flavors, etc.) may be added as well once the paste containing the aqueous humectant, abrasive and thickener is prepared (column 3, lines 18-24; see also column 4, lines 26 (sodium fluoride)). See also the working example at the bottom of column 4, in which a carboxymethyl cellulose suspension is added to a mixture of sorbitol and calcium carbonate abrasive slurry containing the dispersants sodium hexametaphosphate and sodium silicate (also a thickener); auxiliary ingredients include sodium monofluorophosphate and sodium lauryl sulfate (surfactant). The final product contains 41% by weight calcium carbonate ($63.080 \text{ percent calcium carbonate slurry} \times 0.65\% \text{ concentration} = 41\% \text{ calcium carbonate}$).

2) Claims 1-3, 6-8, 10, 12 and 13 are rejected under 35 USC 102(b) as being anticipated by Sanders (USP 2,751,328).

Patentee discloses methods for manufacturing toothpastes in which activation of a carbohydrate binder (thickener) is delayed until substantially all of the solid ingredients have been intimately mixed with substantially all of the liquid ingredients (column 3, lines 18-22). The methods generally comprise (a) dissolving in the various liquid ingredients solid ingredients soluble therein, other than the binder; (b) wetting out and dispersing the hydrophilic colloidal carbohydrate binder in dry comminuted, unhydrated form in a non-hydrating liquid; and (c) combining together all of the principal liquid

Art Unit: 1614

ingredients other than the binder slurry from (b). See the passage bridging column 3, line 74 to column 4, line 8. Where the binder hydrates slowly, however (as in the case of carragenin), a batch operation is employed (column 14, lines 13-17) in which the binder is first allowed to soak for 30-60 minutes (see the passage bridging column 10, line 72 to column 11, line 2). Working example 2 (column 10) illustrates a model process in which a) 38 parts by weight chalk (calcium carbonate) is dissolved in a medium comprising 28 parts water, 30 parts glycerine, 0.9 parts flavor and 2 parts foaming agent (surfactant); b) 1 part sodium carragenin is wetted out in a medium comprising glycerine and water; and c) the two are combined. The average residence time is stated to be about 5 minutes (column 10, lines 67 and 68).

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1614

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 4, 5, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamane et al (USP 6,149,894) in view of Sanders (USP 2,751,328).

The primary reference is discussed in the "Anticipation" section supra and differs from the instant claims insofar as it does not specifically describe incorporating a surfactant or fluoride ion source into the thickener or slurry as required by instant claims 4, 5 and 11, nor does it specify letting the thickening mixture stand long enough to hydrate as required by instant claim 13.

The secondary reference, also discussed in the "Anticipation" section supra, teaches that the order of mixing in toothpaste manufacture is not critical, so long as the thickener is added subsequent to the slurry. See specifically column 3, lines 28 et seq. The secondary reference also teaches at column 2, lines 61-63 that the thickener may be let stand in order to hydrate. Accordingly, it would have been obvious to have varied the order of addition of surfactant or fluoride ion source, and to have permitted the thickener

Art Unit: 1614

to hydrate as illustrated by the secondary reference, consonant with the reasoning of the cited precedent.

2) Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders (USP 2,751,328).

The prior art is discussed previously, and differs from the instant claim insofar as it does not specifically disclose incorporating the surfactant into the thickening mixture. It would have been obvious to have changed the order of addition to do so, however, for the same reasons set forth in subsection “1)” supra.

3) Claims 5, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders (USP 2,751,328) in view of Yamane et al (USP 6,149,894).

The primary reference is discussed supra, and differs from the instant claims in its silence regarding a fluoride ion source or a thickening silica.

Generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. *See Sinclair & Carroll Co. v. Interchemical Corp.*, 325 US 327, 65 USPQ 297 (1945); see also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). The secondary reference, also discussed supra, teaches what is well-known in the art, namely that fluoride ion sources and thickening silicas are conventional toothpaste additives. Accordingly, it would have been obvious to have selected same for incorporation into the toothpastes of the primary reference based on their recognized suitability as toothpaste additives as illustrated by the secondary reference, consonant with reasoning of the cited precedent.

Art Unit: 1614

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

